04-24-00 A

jc806 U.S. PTO
04/21/00

Attorney's Docket No. **760-24 DIV 2**

PATENT

jc135 U.S. PTO
09/556726
04/21/00

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Box Patent Application
Assistant Commissioner for Patents
Washington, D.C. 20231

NEW APPLICATION TRANSMITTAL

Transmitted herewith for filing is the patent application of

Inventor(s): **THOMPSON, Paul J.**, a U.S. citizen, whose address is
9125 40 and ½ Avenue North
New Hope, MN 55427

For (title): **EXPANDABLE STENT-GRAFT COVERED WITH EXPANDED POLYTETRAFLUOROETHYLENE**

09556726 042100

CERTIFICATION UNDER 37 CFR 1.10

I hereby certify that this New Application Transmittal and the documents referred to as enclosed herein are being deposited with the United States Postal Service on this date, **April 21, 2000**, in an envelope as "Express Mail to Addressee" Mailing Label Number **EJ094851698US**, addressed to the Commissioner of Patents and Trademarks, Washington, D.C. 20231.

K.J. Goodhand
Name of person mailing paper

K. J. Goodhand
Signature of person mailing paper

1. Type of Application

This new application is a(n):

[ ] Original (nonprovisional) application.

[ ] Design application.

[ ] Plant application.

[X] Divisional of Serial No. **08/988,725**, filed on **12/11/97**, under

[X] 37 CFR 1.53 [ ] 37 CFR 1.60, which is a division of Serial No. 08/751,884, filed 11/18/96, which claims priority to provisional application No. 60/007,435, filed 11/21/95.

[ ] Continuation of Serial No. **08/_____**, filed on _____, under

[ ] 37 CFR 1.53 [ ] 37 CFR 1.60.

[ ] Continuation-in-part of Serial No. **08/_____**, filed on _____, under

[ ] 37 CFR 1.53 [ ] 37 CFR 1.62.

2. Benefit of Prior U.S. Application(s) (35 U.S.C. 119(e), 120, or 121)

[X] This new application claims the benefit of prior U.S. application(s).

[ ] Please amend the specification by inserting, before the first line, the following:

[ ] "This application claims the benefit of U.S. Provisional Application No. _/_____, filed on _____."

[ ] "This application is a
[ ] continuation
[ ] continuation-in-part
[ ] divisional
of copending application
[ ] Serial No. _____, filed on_____."
[ ] International Application No._____, filed on _____, and which designated the U.S."

[X] A Preliminary Amendment is enclosed amending this application to state the relation of this application to prior applications.

[ ] The relation of this application to prior applications is stated in the application.

3. 35 U.S.C. 119 Priority Claim for Prior Application

This application, and prior U.S. application(s), including any prior International Application designating the U.S., identified above in item 2, claim(s) priority from one or more foreign applications as follows:

(Country)	(Application No.)	(Filing Date)
(Country)	(Application No.)	(Filing Date)
(Country)	(Application No.)	(Filing Date)

Certified copy(ies) of the application(s) from which priority is claimed:

[ ] has(have) been filed on _____, in prior application 08/_____, which was filed on _____.
[ ] is (are) enclosed.
[ ] will follow.

4. Papers Enclosed Which are Required to Obtain Application Filing Date under 37 CFR 1.53(b) (Regular) or 37 CFR 1.153 (Design)

14 Pages of specification
5 Pages of claims
1 Pages of Abstract
6 Sheets of drawings
[ ] formal
[X] informal

[ ] The enclosed drawing(s) include photograph(s), and there is also attached a "Petition to Accept Photograph(s) as Drawings." 37 CFR 1.84(b).

5. Additional Papers Enclosed

[X] Preliminary Amendment

[ ] Information Disclosure Statement (37 CFR 1.98)

[ ] Form PTO-1449

[ ] Citations

[ ] Declaration of Biological Deposit

[ ] Submission of "Sequence Listing," computer readable copy and/or amendment pertaining thereto for biotechnology invention containing nucleotide and/or amino acid sequence

[ ] Authorization of Attorney(s) to Accept and Follow Instructions from Representative

[ ] Special Comments

[ ] Power of Attorney

[ ] Other

6. Declaration or Oath

[ ] A Declaration or Oath is enclosed, executed by (check all applicable boxes):

[ ] inventor(s).

[ ] legal representative(s) of inventors(s) (37 CFR 1.42 or 1.43).

[ ] joint inventor or person showing a proprietary interest on behalf of inventor who refused to sign or cannot be reached.

[ ] This transmittal serves as the petition required under 37 CFR 1.47, and the statement required under 37 CFR 1.47 is also enclosed. See item 13 below for fee.

[X] A Declaration or Oath was filed on **11/18/96** in prior application **08/751,884**, filed on **11/18/96**, from which benefit is being claimed for this application under 35 U.S.C. 120 or 121. The subject matter disclosed in the present application is the same as that disclosed in the prior application, and the inventors are the same or less than those named in the prior application. Accordingly, no new Oath or Declaration is required.

[X] A copy of the Oath or Declaration in the prior application is enclosed.

[ ] A Declaration or Oath is not enclosed.

[ ] Application is made by a person authorized under 37 CFR 1.41(c) on behalf of *all* of the above named inventor(s).

[X] A Power of Attorney is included in the Declaration or Oath.

[X] A copy of a Power of Attorney listing Hoffmann & Baron, LLP as attorneys of record filed on March 2, 2000 in parent application No. 08/988,725 along with a Statement Under 37 C.F.R. §3.73(b) is also enclosed.

7. **Language**

This new application is written in:

[X] English.

[ ] A non-English language: _____.

[ ] A verified translation is enclosed (37 CFR 1.52(d)).

8. **Assignment**

[X] An assignment of the invention to **Schneider (USA) Inc.** _____

[ ] is enclosed. A separate:

[ ] "Cover Sheet for Assignment (Document) Accompanying New Patent Application" is enclosed.

[ ] Form PTO-1595 is enclosed.

[X] was made in prior application No. **08/751,884**, filed on **11/18/96**.

[X] A copy of the assignment (and any recordation cover sheet) is enclosed.

[ ] will follow.

9. **Maintenance of Copendency of Prior Application**

[ ] A Petition for Extension of Time and the appropriate fee has been filed and extends the term in the pending prior application until _____.

[ ] A copy of the petition filed in the prior application is attached.

[ ] A conditional petition for extension of time is being filed in the pending prior application.

[ ] A copy of the conditional petition in the prior application is attached.

10. **Abandonment of Prior Application**

[ ] Please abandon the prior application at a time while the prior application is pending, or when the petition for extension of time or to revive in that application is granted, and when this application is granted a filing date, so as to make this application copending with said prior application.

11. Petition for Suspension of Prosecution for the Time Necessary to File an Amendment

[ ] There is provided herewith a Petition to Suspend Prosecution for the Time Necessary to File an Amendment.

12. Fee Calculation (37 CFR 1.16)

A. **[X]** Regular application (37 CFR 1.16(a)) Basic Fee $690.00

FEES FOR CLAIMS AS FILED							
Number filed			Number extra		Rate		
Total Claims (37 CFR 1.16(c))	7 - 20 =	**0**	X		$ 18.00	=	**$ 0**
Independent Claims (37 CFR 1.16(b))	**2** - 3 =	**0**	X		$ 78.00	=	**$ 0**
Multiple Dependent Claims (37 CFR 1.16(d))			+		$260.00	=	$--------

Fee Calculation for Extra Claims $ **0**

[ ] Amendment canceling extra claims enclosed.

[ ] Amendment deleting multiple-dependencies enclosed.

B. [ ] Design application (37 CFR 1.16(f)) Filing Fee $310.00

C. [ ] Plant application (37 CFR 1.16(g)) Filing Fee $480.00

Total Filing Fee Calculation **$690.00**

13. Request for International-Type Search (37 CFR 1.104(d))

[ ] Please prepare an international-type search report for this application at the time national examination on the merits takes place. See item 15 for fee.

14. Small Entity Statement(s)

[ ] A Verified Statement that this is a filing by a small entity under 37 CFR 1.9 and 1.27;

[ ] is enclosed.
[ ] will follow.

[ ] Status as a small entity was claimed in prior application **08/**_____, filed on _____, from which benefit is being claimed for this application under:

[ ] 35 U.S.C. 119(e),
[ ] 35 U.S.C. 120,
[ ] 35 U.S.C. 121,
[ ] 35 U.S.C. 365(c),

and which status as a small entity is still proper and desired.

[ ] A copy of the verified statement in the prior application is enclosed.

Filing Fee Calculation (50% of **A**, **B**, or **C** above) $_____

15. Fee Payment Being Made at This Time

[ ] Not enclosed. No filing fee is to be paid at this time.

[X] Enclosed:

[X]	Basic filing fee (Item 12 or 14 above)	**$690.00**
[ ]	Fee for recording Assignment ($40.00 (37 CFR 1.21(h)))	$_____
[ ]	Petition fee for filing by other than all of the inventors or person on behalf of the inventor where inventor refused to sign or cannot be reached. ($130.00 (37 CFR 1.47 and 1.17(h)))	$_____
[ ]	Fee for processing an application having a specification in a non-English language. ($130.00 (37 CFR 1.52(d) and 1.17(k)))	$_____
[ ]	Processing and retention fee ($130.00 (37 CFR 1.53(d) and 1.21(l)))	$_____

[ ] Fee for international-type search report ($40.00 (37 CFR 1.21(e))) $_____

Total fees enclosed $**690.00**.

16. Method of Payment of Fees

[X] Check in the amount of $**690.00**.

[ ] Charge Deposit Account No. 08-2461 in the amount of $_____.
A duplicate of this transmittal is enclosed.

17. Authorization to Charge Additional Fees

[X] The Commissioner is hereby authorized to charge the following additional fees by this paper and during the entire pendency of this application to Deposit Account No. 08-2461:

[X] 37 CFR 1.16(a), (f), or (g) (filing fees)

[X] 37 CFR 1.16(b), (c), and (d) (presentation of extra claims)

[ ] 37 CFR 1.16(e) (surcharge for filing the basic fee and/or declaration at a date later than the filing date of the application)

[ ] 37 CFR 1.17 (application processing fees)

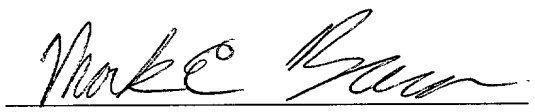
A duplicate of this transmittal is enclosed.

18. Instructions as to Overpayment

[X] Credit Deposit Account 08-2461.

[ ] Refund.

Scanned #Date



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Registration No. 46,150
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(973) 331-1700

PATENT

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Applicant(s): Thompson, P.

Serial No.: Unassigned

Filed: Herewith

For: EXPANDED STENT-GRAFT COVERED WITH EXPANDED POLYTETRAFLUORO-ETHYLENE

Examiner: Unassigned

Group Art Unit: Unassigned

Docket: 760-24 DIV 2

Dated: April 21, 2000

Express Mail Certificate
Date April 21, 2000 Label No EJ094851698US
I hereby certify that on the date indicated above, I deposited this paper or fee with the U.S. Postal Service and that it was addressed for delivery to the Assistant Commissioner For Patents, Washington, D.C. 20231 by "EXPRESS MAIL Post Office to Addressee" service.

K.J. Goodhand
Name (Print)

K.J. Goodhand
(Signature)

Assistant Commissioner for Patents
Washington, DC 20231

PRELIMINARY AMENDMENT PURSUANT TO 37 C.F.R. §1.53 ACCOMPANYING NEW APPLICATION TRANSMITTAL

Sir:

The present submission is being made to accompany a divisional application filed concurrently herewith, claiming priority to co-pending application Serial No. 08/988,725, filed December 11, 1997. That application is a division of Serial No. 08/751,884 filed November 18, 1996, which claims priority to provisional application No. 60/007,435, filed November 21, 1995.

Prior to calculating the filing fee for this application, please amend the application as follows.

IN THE SPECIFICATION:

On page 1, line 4, before "This application", insert --The present application claims priority to and is a divisional application of co-pending application U.S. Serial No. 08/988,725, filed December 11, 1997, which is a divisional application of U.S. Serial No. 08/751,884, filed November 18, 1996, which claims priority to provisional application No. 60/007,435, filed November 21, 1995.--

IN THE CLAIMS:

Please cancel claims 1-18, and 21, and add the following claims.

22. The expandable stent-graft according to claim 19 wherein the tubular layer of expanded polytetrafluoroethylene has (i) a first average longitudinal inter-nodule distance of between about 50 and about 150 microns, and (ii) a second average longitudinal inter-nodule distance of between about 0 and about 50 microns.

23. The expandable stent-graft according to claim 22 wherein the tubular layer of expanded polytetrafluoroethylene has a second average longitudinal inter-nodule distance of between about 5 and about 45 microns.

24. The expandable stent-graft according to claim 23 wherein the tubular layer of expanded polytetrafluoroethylene has a second average longitudinal inter-nodule distance of between about 20 and about 30 microns.

25. The expandable stent-graft according to claim 22 wherein the tubular layer of expanded polytetrafluoroethylene has a first average longitudinal inter-nodule distance of between about 60 and about 140 microns.

26. The expandable stent-graft according to claim 25 wherein the tubular layer of expanded polytetrafluoroethylene has a first average longitudinal inter-nodule distance of between about 80 and about 120 microns.

REMARKS

The application accompanying this Preliminary Amendment is a divisional application directed to claims 19-20 elected out of co-pending Serial No. 08/988,725, filed December 11, 1997. Accordingly, claims 1-18 and 21 have been cancelled. New claims 22-26 have been added.

Applicant respectfully submits that the application including claims 19-20 and 22-26 is in condition for allowance and favorable action is therefore solicited. Should the Examiner have any questions the undersigned would be pleased to address them by telephone.

Respectfully submitted,

Mark E. Baron
Registration No.: 46,150
Attorney for Applicant(s)

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EXPANDABLE STENT-GRAFT COVERED WITH EXPANDED POLYTETRAFLUOROETHYLENE

This application claims the benefit of United States Provisional Application No. 60/007,435, entitled EXPANDABLE STENT GRAFT COVERED WITH EXPANDED POLYTETRAFLUOROETHYLENE, filed November 21, 1995.

BACKGROUND OF THE INVENTION

The present invention is generally directed to an expandable stent-graft made from a stent covered with expanded polytetrafluoroethylene.

The use of covered expandable stent-grafts for bodily lumen repair is known in the art. Covered expandable stent- grafts may be implanted in a radially compressed state, generally using a catheter, into blood vessels, urinary tracts, biliary tracts, esophageal, femoralpopliteac, venous, iliac, arterial-venus, venus cava, tracheo bronchial, abdominal aorta, thoracic aorta, coronary arteries, carotid arteries, colonic, fallopian, eustachian, ureter, urethra, prostrate or virtually any duct, gorge, or body chamber in a body.

The expandable stent-graft is generally positioned and released from a delivery catheter at a damaged area as desired. Expandable stent-grafts provide outward pressure and support for the body lumen walls, thus creating improved passageways. The addition of a covering on an expandable stent acts to reduce cell growth or occlusions in the interior of the lumen.

Coverings and covered expandable stents that are known in the art are disclosed in the following documents: U.S. Patent Nos. 3,953,566 to Gore; 4,655,771 to Wallsten; 5,061,275 to Wallsten et al; 5,112,900 to Buddenhagen et al; 5,123,917 to Lee; 5,282,823 to Schwartz et al; 5,282,824 to Gianturco, 4,850,999 to Planck, European Patent Application No. 0 621 015 A1 to Lukic, European Patent Application No. 0 551 179 A1 to Palmaz, DE 3918736-A1 to Vallbracht, Patent Cooperation Treaty Application WO 95/05131 to Gore, Patent Cooperation Treaty Application WO 95/05132 to Gore, Patent Cooperation Treaty Application WO 95/05555 to Gore; Patent Cooperation Treaty Application WO 87/04935 to Fischell. (All documents cited herein, including the foregoing, are incorporated herein in their entireties for all purposes.)

It is an object of the present invention to provide an expandable stent-graft which is covered, at least in part, with expanded polytetrafluoroethylene (ePTFE).

Other objects of the invention will become apparent to those skilled in the art through familiarization with the specification and claims herein.

SUMMARY OF THE INVENTION

The expandable stent-graft of the present invention is designed to provide an expanded polytetrafluoroethylene covering that expands and compresses in association with the stent structure as the stent structure expands and contracts. The expandable stent-graft of the present invention may be used for repair and support of body vessel walls.

In preferred embodiments of the present invention, an expandable stent-graft includes a bonded layer of expanded polytetrafluoroethylene covering a stent so that the longitudinal fibrils of the cover are at least substantially extended to adapt to the stent longitudinal expansion when the stent is radially compressed; circumferential fibrils are at least substantially folded to adapt to the stent radial compression when the stent is longitudinally expanded; longitudinal fibrils are at least substantially folded to adapt to the stent longitudinal compression when the stent is radially expanded; and so the circumferential fibrils are at least substantially extended to adapt to the stent radial expansion when the stent is longitudinally compressed.

In other preferred embodiments of the present invention, an expandable stent-graft includes a bonded layer of expanded polytetrafluoroethylene covering a stent so that the inter-nodule distance measured in the longitudinal direction between nodules is increased when the expandable stent-graft is radially compressed; the inter-nodule distance measured in the longitudinal direction between nodules is decreased when the expandable stent-graft is radially expanded; the inter-nodule distance measured in the circumferential direction between nodules is increased when the expandable stent-graft is longitudinally compressed; and so the inter-nodule distance measured in the circumferential direction between nodules is decreased when the expandable stent-graft is longitudinally expanded.

In sum, the present invention relates to an expandable prosthesis having (a) a discontinuous wall defining a lumen adapted to assume a longitudinally contracted position and a longitudinally expanded position; and (b) at least one layer of expanded polytetrafluoroethylene having a first average longitudinal inter-nodule distance in a free state, the layer of polytetrafluoroethylene affixed to the wall such that it has a second average longitudinal inter-nodule distance when the wall is in the longitudinally contracted position, the second average longitudinal inter-nodule distance being less than the first average longitudinal inter-nodule distance. The layer of expanded polytetrafluoroethylene may have (i) an average longitudinal inter-nodule distance of between about 0 and about 50 microns, preferably between about 5 and about 45 or between about 20 and about 30 microns, when the wall is in the longitudinally contracted position, and (ii) an average longitudinal inter-nodule distance of between about 50 and about 150 microns, preferably between about 60 and about 14 or between about 80 and about 120 microns, when the wall is in the longitudinally expanded position.

The present invention also relates to an expandable prosthesis having (a) a discontinuous wall defining a lumen adapted to assume a radially contracted position and a radially expanded position; and (b) at least one tubular layer of an expanded polytetrafluoroethylene having a first average circumferential inter-nodule distance in a free state, the layer of polytetrafluoroethylene affixed to the wall such that it has a second average circumferential inter-nodule distance when the wall is in the radially contracted state, the second average circumferential inter-nodule distance being less than the first average circumferential inter-nodule distance. The tubular layer of expanded polytetrafluoroethylene may have (i) an average circumferential inter-nodule distance of between about 0 and about 75 microns, preferably between about 5 and about 70 or between about 20 and about 50 microns, when the wall is in the radially contracted position, and (ii) an average circumferential inter-nodule distance of between about 75 and about 150 microns, preferably between about 80 and about 140 microns or between about 80 and about 120 microns, when the wall is in the radially expanded position.

The present invention also relates to an expandable prosthesis having (a) a discontinuous wall generally defining a lumen adapted to assume a longitudinally

expanded position and a longitudinally contracted position; and (b) at least one layer of expanded polytetrafluoroethylene having a first average longitudinal inter-nodule distance in a free state, the layer of polytetrafluoroethylene affixed to the wall such that the polytetrafluoroethylene has a second average longitudinal inter-nodule distance between 0 and 99 percent of the first average longitudinal inter-nodule distance when the wall is in the longitudinally contracted position. The second average longitudinal inter-nodule distance may be between about 20 and about 50 percent of the first average longitudinal inter-nodule distance when the wall is in the longitudinally contracted position.

The present invention also relates to an expandable prosthesis having (a) a discontinuous wall generally defining a lumen adapted to assume a radially expanded position and a radially contracted position; and (b) at least one layer of expanded polytetrafluoroethylene having a first average circumferential inter-nodule distance in a free state, the layer of polytetrafluoroethylene affixed to the wall such that the polytetrafluoroethylene has a second average circumferential inter-nodule distance less than about 50 percent of the first average circumferential inter-nodule distance when the wall is in the radially contracted position. The second average circumferential inter-nodule distance may be less than about 25 percent of the first average circumferential inter-nodule distance when the wall is in the radially contracted position.

The present invention also relates to an expandable prosthesis having (a) a discontinuous wall defining a lumen adapted to assume a radially expanded position and a radially contracted position; and (b) at least one layer of expanded polytetrafluoroethylene having a first average longitudinal inter-nodule distance and a first average circumferential inter-nodule distance in a free state, the layer of the polytetrafluoroethylene affixed to the wall such that the polytetrafluoroethylene has a second average longitudinal inter-nodule distance between 0 and 99 percent of the first average longitudinal inter-nodule distance when the wall is in the radially expanded position and a second average circumferential inter-nodule distance less than about 50 percent of the first average circumferential inter-nodule distance when the wall is in the radially contracted position. The second average longitudinal inter-nodule distance may be between about 20 and about 50 percent

of the first average longitudinal inter-nodule distance, and the second average circumferential inter-nodule distance may be less than about 25 percent of the first average circumferential inter-nodule distance.

The present invention also relates to an expandable stent-graft having (a) a braided self-expanding stent characterized by a longitudinal shortening upon radial expansion from a first longitudinal stent length to a second longitudinal stent length; and (b) at least one tubular layer of biaxially oriented expanded polytetrafluoroethylene comprising nodules and fibrils affixed to the stent characterized by a shortening of average longitudinal inter-nodule distance upon radial expansion from a first average longitudinal inter-nodule distance to a second average longitudinal inter-nodule distance; wherein the ratio of first longitudinal stent length to second longitudinal stent length is within about 25 percent of, and is preferably substantially the same as, the ratio of first average longitudinal inter-nodule distance to a second average inter-nodule distance. The present invention also relates an expandable stent-graft having (a) a braided self-expanding stent characterized by a longitudinal shortening upon radial expansion; (b) at least one layer of uniaxially oriented expanded polytetrafluoroethylene affixed to the stent, the polytetrafluoroethylene characterized by having substantially no nodules.

The present invention also relates to a method of making an expandable prosthesis including (a) providing a self-expanding braided stent having a longitudinal orientation in an at least partially radially expanded state; (b) providing at least one layer of expanded polytetrafluoroethylene having a longitudinal orientation and a first average longitudinal inter-nodule distance in a free state; (c) longitudinally compressing the layer of expanded polytetrafluoroethylene so that the resulting longitudinally compressed layer has a second average longitudinal inter-nodule distance which is less than the first average longitudinal inter-nodule distance; and (d) affixing the longitudinally compressed layer of expanded polytetrafluoroethylene to the self-expanding braided stent in the at least partially radially expanded state such that the longitudinal orientations of the stent and layer of expanded polytetrafluoroethylene substantially correspond with one another.

BRIEF DESCRIPTION OF THE DRAWINGS

The foregoing features, objects and advantages of the present invention will become apparent to those skilled in the art from the following detailed description of preferred embodiments, especially when considered in conjunction with the accompanying drawings in which:

Figure 1 depicts a micrograph view showing the nodules and fibrils of a biaxially oriented, expanded polytetrafluoroethylene material at a 2000X magnification.

Figure 2 depicts an illustration of the nodule and fibril relationship and the inter-nodule distances of a biaxially oriented, expanded polytetrafluoroethylene material on a stent that is longitudinally compressed.

Figure 3 depicts a view of the nodule and fibril relationship and the inter-nodule distances of a biaxially oriented, expanded polytetrafluoroethylene material on a stent that is radially compressed.

Figures 4-12 illustrates steps of making the expandable stent-graft according to the present invention, wherein:

Figure 4 depicts a mandrel;

Figure 5 depicts the biaxially oriented expanded polytetrafluoroethylene (ePTFE) material (tube, sheet or strips or any combination of tube, sheet or strips) at least partially covering the mandrel;

Figure 6 depicts the ePTFE material being longitudinally compressed onto the mandrel and further illustrates the longitudinal fibrils being substantially folded and the circumferential fibrils allowed to remain substantially extended;

Figure 7 depicts an expanded stent, having an inside diameter greater than the combined outside diameter of the mandrel and the ePTFE material, being positioned over the longitudinally compressed ePTFE material on the mandrel;

Figure 8 depicts a section view of the stent over the longitudinally compressed ePTFE material;

Figure 9 depicts an end view of the stent over the longitudinally compressed ePTFE material;

Figure 10 depicts an outer layer of longitudinally compressed ePTFE material positioned over the stent, an inner layer of longitudinally compressed ePTFE material and the mandrel;

Figure 11 depicts a section view of an outer layer of longitudinally compressed ePTFE material positioned over the stent and an inner layer of longitudinally compressed ePTFE material. The ePTFE materials are bonded over or throughout the outside surface, inside surface or throughout the discontinuous wall of the stent; and

Figure 12 depicts an end view of an outer layer of longitudinally compressed ePTFE material positioned over the stent and an inner layer of longitudinally compressed ePTFE material. The ePTFE materials are bonded over or throughout the outside surface, inside surface or throughout the discontinuous wall of the stent.

Figure 13 depicts an illustration of the various states of the ePTFE on the stent such as when the expandable stent- graft is radially compressed or radially expanded.

DESCRIPTION OF THE PREFERRED EMBODIMENTS

Referring now to FIGS. 1-3, the present invention relates to a flexible and generally cylindrical expandable stent-graft **20** that may be made from a stent **12** and a covering of biaxially oriented, expanded polytetrafluoroethylene material **3**. The biaxially oriented, expanded polytetrafluoroethylene material **3** has a microstructure comprised of nodules **2** and fibrils **4, 4'** and inter-nodule distances $\alpha, \alpha', \theta, \theta'$.

The term biaxial, expanded polytetrafluoroethylene material as used herein means a biaxially oriented expanded polytetrafluoroethylene material. The term uniaxial, expanded polytetrafluoroethylene material as used herein means a uniaxially oriented expanded polytetrafluoroethylene material. The average longitudinal inter-nodule distance of either uniaxial or biaxial expanded polytetrafluoroethylene may be between about 5 and about 150 microns in the free state, preferably between about 20 and about 60 microns in the free state. The longitudinal orientation and resulting longitudinal inter-nodule distances are based on the orientation when the expanded polytetrafluoroethylene is placed on a stent,

such that the longitudinal orientation of the stent and expanded polytetrafluoroethylene substantially correspond with one another. The expanded polytetrafluoroethylene is in a free state when no force is applied thereto.

A preferred embodiment of the expandable stent-graft **20** of the present invention may be designed so that its expanded polytetrafluoroethylene covering **10'** is associated with the expansion or compression of the stent **12** (FIG. 13), as the expandable stent-graft **20** is inserted in a delivery catheter or deployed into a body lumen. The expandable stent-graft **20** is intended for repair and support of body vessel walls.

A preferred embodiment of the expandable stent-graft **20** of the present invention may be made from a braided stent **12** such as the one described in U.S. Patent No. 5,061,275 to Wallsten. Such a self-expanding stent is characterized in that the stent longitudinally contracts as it radially expands, and longitudinally expands as it radially contracts. Other, non-braided stents are known in the art which share this characteristic. This stent **12** may be at least partially covered, individually or in combination, with at least one layer of tube, sheet, strips or film of biaxial expanded polytetrafluoroethylene material **10** on the inside surface **14**, outside surface **18**, inside surface **14** and outside surface **18**, or between the inside surface **14** and the outside surface **18** of the discontinuous wall of a stent **12** (FIGS. 7-13). The stent **12** and expanded polytetrafluoroethylene covering **10'** may be bonded together, for instance under heat and pressure, to form the expandable stent-graft **20**. Another method of bonding may include the use of another polymer such as a polyurethane or FEP which has a lower melt point.

The expandable stent-graft **20** of the present invention offers the properties of a stent **12** and the benefits of an expanded polytetrafluoroethylene covering that conforms to the compliance and distortion of the underlying stent **12**. The expanded polytetrafluoroethylene microstructure (FIGS. 1-3) and it's orientation on the stent **12** (FIGS. 5-13) relate to the present invention. The expandable stent-graft **20** has characteristics that may reduce the occlusion of the lumen and improve healing of the damaged body vessels.

Another preferred embodiment of the expandable stent- graft **20** of the present invention may comprise a uniaxial, expanded polytetrafluoroethylene

covering on at least part of the inside surface **14**, outside surface **18,** inside surface **14** and outside surface **18** or between the inside surface **14** and the outside surface **18** of the stent **12**. The uniaxial, expanded polytetrafluoroethylene covering may be comprised substantially of fibrils as the nodules have been reduced substantially to zero. Other uniaxial, expanded polytetrafluoroethylene coverings may have discrete nodules so that the nodules are substantially unconnected to one another.

Another preferred embodiment of the expandable stent- graft **20** of the present invention may comprise a uniaxial, expanded polytetrafluoroethylene covering and a biaxial, expanded polytetrafluoroethylene covering **10'** on at least part of the inside surface **14**, outside surface **18,** inside surface **14** and outside surface **18,** or between the inside surface **14** and the outside surface **18** of the stent **12**. The uniaxial, expanded polytetrafluoroethylene covering is comprised substantially of fibrils and is longitudinally oriented on the stent.

In these preferred embodiments, the expanded polytetrafluoroethylene covering may correspondingly expand and contract with the stent **12**. As radial and longitudinal forces are applied to the expandable stent-graft (FIG. 13), the nodule and fibril relationship may change within the biaxial expanded polytetrafluoroethylene material **10'** and the fibril relationship within the uniaxial expanded polytetrafluoroethylene material and allows the covering to conform to the shape to of the stent **12**. FIG. 13 illustrates an expandable stent-graft of the present invention with the end portions in at least partially radially expanded states and the mid-section in an at least partially radially contracted state.

In the preferred embodiments of the expandable stent- graft **20** of the present invention, the preferred nodule and fibril relationship of the biaxial, expanded polytetrafluoroethylene or the preferred fibril relationship of the uniaxial expanded polytetrafluoroethylene material is dependent on the dimensions of the stent **12** being covered. However, the preferred nodule and fibril relationship of the biaxial, expanded polytetrafluoroethylene in the free state or the preferred fibril relationship of the uniaxial, expanded polytetrafluoroethylene in the free state may have a circumferential fibril length ranging from about 5 microns to about 150 microns; an inter-nodule distance measured in the circumferential direction ranging

from about 5 microns to about 150 microns; a longitudinal fibril length ranging from about 5 microns to about 100 microns; or an inter-nodule distance measured in the longitudinal direction ranging from about 5 microns to about 100 microns to be sufficient to offer the desired range of performance for the present invention.

The nodules **2** and fibrils **4, 4'** within the biaxial, expanded polytetrafluoroethylene material may be oriented onto the stent **12** so that the longitudinal fibrils are at least substantially extended **4'** to adapt to the stent **12** longitudinal expansion when the stent **12** is radially compressed; the circumferential fibrils are at least substantially folded **6'** to adapt to the stent radial compression when the stent **12** is longitudinally expanded; the longitudinal fibrils are at least substantially folded **4** to adapt to the stent **12** longitudinal compression when the stent **12** is radially expanded; or the circumferential fibrils are at least substantially extended **6** to adapt to the stent radial expansion when the stent **12** is longitudinally compressed (FIGS. 6, 7, 10, and 13). The interaction of the nodules **2** and fibrils **4, 4'** within the biaxial, expanded polytetrafluoroethylene material **10'** allows the biaxial, expanded polytetrafluoroethylene material **10'** to substantially conform to the radial and longitudinal expansion and compression of the stent **12**.

The present invention also relates to a method of bonding an expanded polytetrafluoroethylene material **10, 10'** onto a stent **12** so that the inter-nodule distance measured in the longitudinal direction between nodules is increased when the expandable stent-graft **20** is radially compressed; the inter-nodule distance measured in the longitudinal direction between nodules is decreased when the expandable stent-graft **20** is radially expanded; the inter-nodule distance measured in the circumferential direction between nodules **2** is increased when the expandable stent-graft **20** is longitudinally compressed; or the inter-nodule distance measured in the circumferential direction between nodules **2** is decreased when the expandable stent-graft is longitudinally expanded.

The stent **12** and expanded polytetrafluoroethylene covering **10'** substantially are bonded together and substantially coextensively compress, expand or conform in shape, when radial and longitudinal forces expand or compress the expandable stent-graft **20**. For example, the expandable stent-graft

20 may compress when inserted into a delivery catheter or the expandable stent-graft **20** may expand when deployed from the catheter into a body vessel.

The biaxial, expanded polytetrafluoroethylene **10, 10'** or uniaxial, expanded polytetrafluoroethylene covering are not elastomers, yet, they each expand and contract with the radial or longitudinal expansion and compression forces on the expandable stent-graft **20**. Also, the biaxial expanded polytetrafluoroethylene or uniaxial expanded polytetrafluoroethylene coverings may expand and compress on the expandable stent-graft **20** and have reduced folds, flaps, pillowing or kinks, thus, reducing the thrombogenic effect that may result from uneven or rough vessel surfaces. The orientation of the ePTFE and the interaction of the nodules **2** and fibrils **4, 4', 6, 6'** may allow the inside surface **14** and/or the outside surface **18** to be substantially smooth in both contracted and expanded states.

Another preferred embodiment of the expandable stent-graft **20** of the present invention offers a substantially smooth covering during the radial and longitudinal compression and expansion of the expandable stent-graft **20**. Radial compression and longitudinal expansion of the expandable stent-graft **20** occurs when the expandable stent-graft **20** is inserted into a catheter. Radial expansion and longitudinal compression of the expandable stent-graft **20** occurs when the expandable stent-graft **20** is deployed into various sized body vessels.

The expandable stent-graft **20** of the present invention may provide a surface that promotes increased fluid flow, reduced fluid turbulence, and overall improved compliance properties when compared to conventional covered stents. Many of the present invention characteristics are desired by medical practitioners, when repairing and healing body vessels.

When compared to an uncovered stent **12**, the expanded polytetrafluoroethylene covering on the stent **12** requires little additional force to expand or contract. The biaxial, expanded polytetrafluoroethylene material **10'** or uniaxial expanded polytetrafluoroethylene material substantially adapts to the radial and longitudinal expansion and compression of the stent **12**. The expanded polytetrafluoroethylene covering is intended to enhance the benefits of a conventional stent **12** by adding graft capabilities, without, reducing the compliance or performance of the expandable stent-graft **20**.

The expandable stent-graft **20** is generally made in the shape of a cylindrical lumen having a discontinuous wall covered with expanded polytetrafluoroethylene.

A preferred embodiment of the expandable stent-graft of the present invention has a nodule and fibril relationship in the biaxial, expanded polytetrafluoroethylene covering **10'** or a fibril relationship in the uniaxial, expanded polytetrafluoroethylene covering, respectively, such that the expandable stent-graft **20** expands longitudinally up to about 300% when radially compressed as compared to it's length when in a radially expanded state.

Another preferred embodiment of the expandable stent-graft **20** of the present invention has a nodule and fibril relationship in the biaxial, expanded polytetrafluoroethylene covering **10'** or a fibril relationship in the uniaxial, expanded polytetrafluoroethylene covering such that the expandable stent-graft **20** expands radially up to about 1000% of its fully radially compressed diameter measurement.

Another preferred embodiments of the expandable stent-graft **20** of the present invention may comprise at least one partial layer of biaxial, expanded polytetrafluoroethylene or a uniaxial **10'**, expanded polytetrafluoroethylene or a combination of a biaxial, expanded polytetrafluoroethylene **10'** and a uniaxial, expanded polytetrafluoroethylene material. The uniaxial, expanded polytetrafluoroethylene material has a fibril relationship and is comprised substantially of fibrils as the nodules **2** have been reduced essentially to nearly zero. Each layer of biaxial or uniaxial, expanded polytetrafluoroethylene material may have a thickness ranging from about 10 to about 500 microns and may be made from tube, sheet, film or a plurality of strips disposed on the inner surface **14** of the discontinuous wall, outer surface **18** of the discontinuous wall, both the inner surface **14** and outer surface **18** of the discontinuous wall of the stent or between the inner surface **14** and outer surface **18** of the discontinuous wall of the stent **12** including the voids between the mesh of the walls. The discontinuous wall and the expanded polytetrafluoroethylene material are bonded at a temperature range of about 340°C to about 390°C.

In a further embodiment of the expandable stent-graft **20** of the present invention, the discontinuous wall of the stent **12** may be coated with expanded

polytetrafluoroethylene, polytetrafluoroethylene or both expanded polytetrafluoroethylene and polytetrafluoroethylene on at least part of its surface.

The preferred embodiments of the expandable stent-graft **20** of the present invention, may be produced by the method of placing a biaxial expanded polytetrafluoroethylene material **10** on a mandrel **8** in an at least partially expanded state, and then longitudinally compressing the biaxial, expanded polytetrafluoroethylene material **10** while it is positioned on the mandrel **8** so that the longitudinal fibrils are at least substantially folded **4** and the circumferential fibrils are at least substantially extended **6** or so that the inter-nodule distance measured in the longitudinal direction between nodules **2** is decreased and the inter-nodule distance measured in the circumferential direction between nodules **2** is increased. A stent **12** having an inside diameter greater than the combined diameter of the expanded polytetrafluoroethylene material and the mandrel **8** is then placed onto the outer surface of the expanded polytetrafluoroethylene material. Contact is then maintained between the stent and the expanded polytetrafluoroethylene material while the covering and the stent are heated to a temperature ranging from about 340°C to about 390°C for a time ranging from about 1 minute to about 15 minutes to bond the expanded polytetrafluoroethylene material to the discontinuous wall of the stent. The expandable stent-graft is then cooled and removed from the mandrel.

Additionally, the preferred embodiments of the expandable stent-graft of the present invention may also be produced by the method of placing a biaxial expanded polytetrafluoroethylene material on a mandrel and then longitudinally expanding or stretching the biaxial, expanded polytetrafluoroethylene material while it is positioned on the mandrel so that the longitudinal fibrils are at least substantially extended and the circumferential fibrils are at least substantially folded. Also, the inter-nodule distance measured in the longitudinal direction between nodules **2** may be increased and the inter-nodule distance measured in the circumferential direction between nodules **2** may be decreased. A stent having a diameter greater than the combined diameter of the expanded polytetrafluoroethylene material and the mandrel is then placed onto the outer surface of the expanded polytetrafluoroethylene material. The expandable stent-

graft is radially compressed and contact is then maintained between the stent and the expanded polytetrafluoroethylene material while the covering and the stent are heated to a temperature ranging from about 340°C to about 390°C for a time ranging from about 1 minute to about 15 minutes to bond the expanded polytetrafluoroethylene material to the discontinuous wall of the stent. The expandable stent-graft is then cooled and removed from the mandrel.

The preferred embodiment of the expandable stent-graft of the present invention may also be produced by longitudinally compressing the expanded polytetrafluoroethylene material, prior to the step of placing the expanded polytetrafluoroethylene material on the mandrel.

The preferred embodiment of the expandable stent-graft of the present invention may also be produced by longitudinally expanding or stretching the expanded polytetrafluoroethylene material prior to the step of placing the expanded polytetrafluoroethylene material on the mandrel. An expanded polytetrafluoroethylene tape can be diagonally wound under tension about an at least partially expanded stent. Additional compressible and expandable objects of varying size, shape, compliance or dimension may also be able to take advantage of the expanded polytetrafluoroethylene coverings.

This invention has been described herein in considerable detail to comply with the Patent Statutes and to provide those skilled in the art with the information needed to apply the novel principles and to construct and use such specialized components as are required. However, it is to be understood that the invention can be carried out by specifically different equipment and devices, and that various modifications, both as to the equipment details and procedures, can be accomplished without departing from the scope of the invention itself. Therefore, the spirit and scope of the claims should not be limited to the description of the preferred versions contained herein.

What is claimed is:

CLAIMS

1. An expandable prosthesis comprising:

(a) a discontinuous wall defining a lumen adapted to assume a longitudinally contracted position and a longitudinally expanded position; and

(b) at least one layer of expanded polytetrafluoroethylene having a first average longitudinal inter-nodule distance in a free state, the layer of polytetrafluoroethylene affixed to the wall such that it has a second average longitudinal inter-nodule distance when the wall is in the longitudinally contracted position, the second average longitudinal inter-nodule distance being less than the first average longitudinal inter-nodule distance.

2. The prosthesis of claim 1 wherein the layer of expanded polytetrafluoroethylene has (i) an average longitudinal inter-nodule distance of between about 0 and about 50 microns when the wall is in the longitudinally contracted position, and (ii) an average longitudinal inter-nodule distance of between about 50 and about 150 microns when the wall is in the longitudinally expanded position.

3. The prosthesis of claim 2 wherein the layer of expanded polytetrafluoroethylene has (i) an average longitudinal inter-nodule distance when the wall is in the longitudinally contracted position of between about 5 and about 45 microns.

4. The prosthesis of claim 3 wherein the layer of expanded polytetrafluoroethylene has (i) an average longitudinal inter-nodule distance when the wall is in the longitudinally contracted position of between about 20 and about 30 microns.

5. The prosthesis of claim 2 wherein the layer of expanded polytetrafluoroethylene has (ii) an average longitudinal inter-nodule distance when the wall is in the longitudinally expanded position of between about 60 and about 140 microns.

6. The prosthesis of claim 5 wherein the layer of expanded polytetrafluoroethylene has (ii) an average longitudinal inter-nodule distance when the wall is in the longitudinally expanded position of between about 80 and about 120 microns.

7. An expandable prosthesis comprising:

(a) a discontinuous wall defining a lumen adapted to assume a radially contracted position and a radially expanded position; and

(b) at least one tubular layer of an expanded polytetrafluoroethylene having a first average circumferential inter-nodule distance in a free state, the layer of polytetrafluoroethylene affixed to the wall such that it has a second average circumferential inter-nodule distance when the wall is in the radially contracted state, the second average circumferential inter-nodule distance being less than the first average circumferential inter-nodule distance.

8. The prosthesis of claim 7 wherein the tubular layer of expanded polytetrafluoroethylene has (i) an average circumferential inter-nodule distance of between about 0 and about 75 microns when the wall is in the radially contracted position, and (ii) an average circumferential inter-nodule distance of between about 75 and about 150 microns when the wall is in the radially expanded position.

9. The prosthesis of claim 8 wherein the tubular layer of expanded polytetrafluoroethylene has (i) an average circumferential inter-nodule distance of between about 5 and about 70 microns when the wall is in the radially contracted position.

10. The prosthesis of claim 9 wherein the tubular layer of expanded polytetrafluoroethylene has (i) an average circumferential inter-nodule distance of between about 20 and about 50 microns when the wall is in the radially contracted position.

11. The prosthesis of claim 8 wherein the tubular layer of expanded polytetrafluoroethylene has (ii) an average circumferential inter-nodule distance of between about 80 and about 140 microns when the wall is in the radially expanded position.

12. The prosthesis of claim 11 wherein the tubular layer of expanded polytetrafluoroethylene has (ii) an average circumferential inter-nodule distance of between about 80 and about 120 microns when the wall is in the radially expanded position.

13. An expandable prosthesis comprising:

(a) a discontinuous wall generally defining a lumen adapted to assume a longitudinally expanded position and a longitudinally contracted position; and

(b) at least one layer of expanded polytetrafluoroethylene having a first average longitudinal inter-nodule distance in a free state, the layer of polytetrafluoroethylene affixed to the wall such that the polytetrafluoroethylene has a second average longitudinal inter-nodule distance between 0 and 99 percent of the first average longitudinal inter-nodule distance when the wall is in the longitudinally contracted position.

14. The prosthesis of claim 13 wherein the second average longitudinal inter-nodule distance is between about 20 and about 50 percent of the first average longitudinal inter-nodule distance when the wall is in the longitudinally contracted position.

15. An expandable prosthesis comprising:

(a) a discontinuous wall generally defining a lumen adapted to assume a radially expanded position and a radially contracted position; and

(b) at least one layer of expanded polytetrafluoroethylene having a first average circumferential inter-nodule distance in a free state, the layer of polytetrafluoroethylene affixed to the wall such that the polytetrafluoroethylene has a second average circumferential inter-nodule distance less than about 50 percent of the first average circumferential inter-nodule distance when the wall is in the radially contracted position.

16. The prosthesis of claim 15 wherein the second average circumferential inter-nodule distance is less than about 25 percent of the first average circumferential inter-nodule distance when the wall is in the radially contracted position.

17. An expandable prosthesis comprising:

(a) a discontinuous wall defining a lumen adapted to assume a radially expanded position and a radially contracted position; and

(b) at least one layer of expanded polytetrafluoroethylene having a first average longitudinal inter-nodule distance and a first average circumferential inter-nodule distance in a free state, the layer of the polytetrafluoroethylene affixed to the wall such that the polytetrafluoroethylene has a second average longitudinal inter-nodule distance between 0 and 99 percent of the first average longitudinal inter-nodule distance when the wall is in the radially expanded position and a second average circumferential inter-nodule distance less than about 50 percent of the first average circumferential inter-nodule distance when the wall is in the radially contracted position.

18. The prosthesis of claim 17 wherein the second average longitudinal inter-nodule distance is between about 20 and about 50 percent of the first average longitudinal inter-nodule distance, and the second average circumferential inter-nodule distance is less than about 25 percent of the first average circumferential inter-nodule distance.

19. An expandable stent-graft comprising:

(a) a braided self-expanding stent characterized by a longitudinal shortening upon radial expansion from a first longitudinal stent length to a second longitudinal stent length; and

(b) at least one tubular layer of biaxially oriented expanded polytetrafluoroethylene comprising nodules and fibrils affixed to the stent characterized by a shortening of average longitudinal inter-nodule distance upon radial expansion from a first average longitudinal inter-nodule distance to a second average longitudinal inter-nodule distance;

wherein the ratio of first longitudinal stent length to second longitudinal stent length is within about 25 percent of the ratio of first average longitudinal inter-nodule distance to a second average inter-nodule distance.

20. An expandable stent-graft comprising:

(a) a braided self-expanding stent characterized by a longitudinal shortening upon radial expansion;

(b) at least one layer of uniaxially oriented expanded polytetrafluoroethylene affixed to the stent, the polytetrafluoroethylene characterized by having substantially no nodules.

21. A method of making an expandable prosthesis comprising:

(a) providing a self-expanding braided stent having a longitudinal orientation in an at least partially radially expanded state;

(b) providing at least one layer of expanded polytetrafluoroethylene having a longitudinal orientation and a first average longitudinal inter-nodule distance in a free state;

(c) longitudinally compressing the layer of expanded polytetrafluoroethylene so that the resulting longitudinally compressed layer has a second average longitudinal inter-nodule distance which is less than the first average longitudinal inter-nodule distance; and

(d) affixing the longitudinally compressed layer of expanded polytetrafluoroethylene to the self-expanding braided stent in the at least partially radially expanded state such that the longitudinal orientations of the stent and layer of expanded polytetrafluoroethylene substantially correspond with one another.

ABSTRACT

The expandable stent-graft generally defines a cylindrical lumen made from a stent having a discontinuous wall that is at least substantially covered with an expanded polytetrafluoroethylene material. The expanded polytetrafluoroethylene covering may be a biaxially oriented, expanded polytetrafluoroethylene material having nodules and longitudinal and circumferential fibrils or a uniaxially oriented, expanded polytetrafluoroethylene material. The expandable stent-graft expands and compresses in association with the stent structure as it is contracted and expanded.

FIG. 1

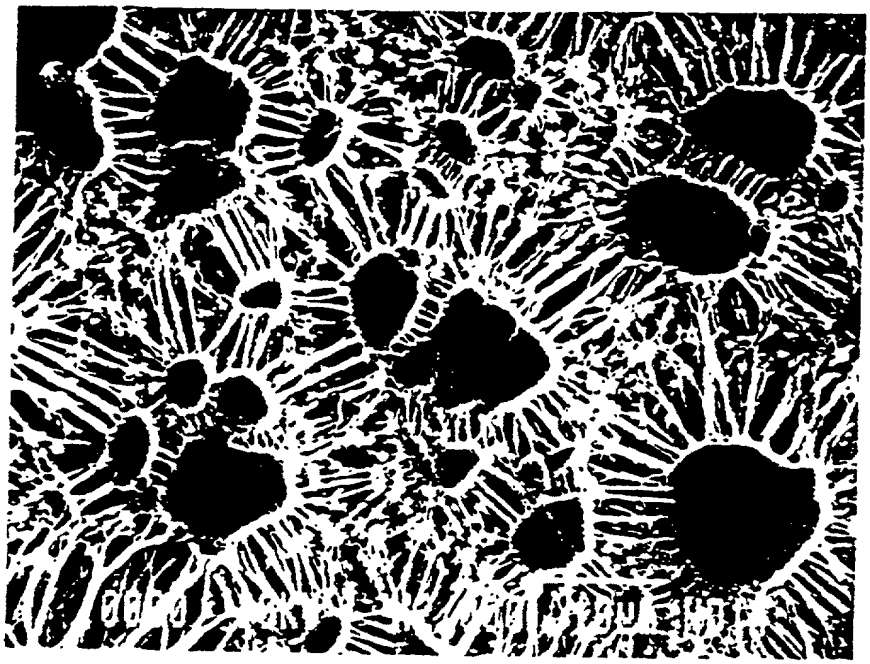

FIG. 2

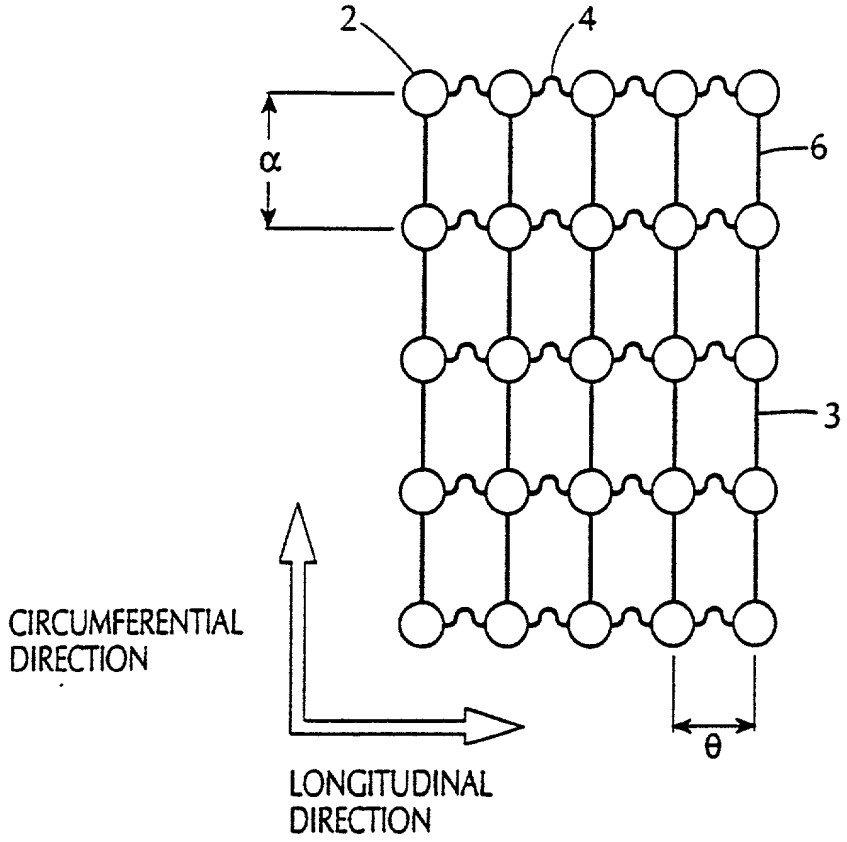
2
4
α
6
3
CIRCUMFERENTIAL DIRECTION
θ
LONGITUDINAL DIRECTION

FIG. 3

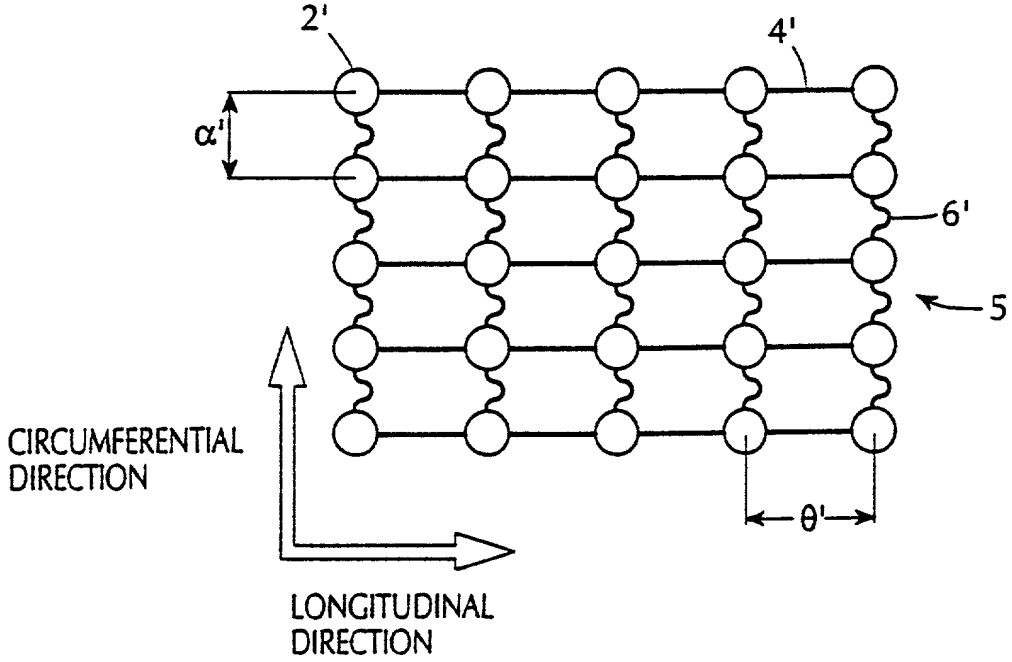
2'
4'
α'
6'
5
CIRCUMFERENTIAL DIRECTION
θ'
LONGITUDINAL DIRECTION

FIG. 4

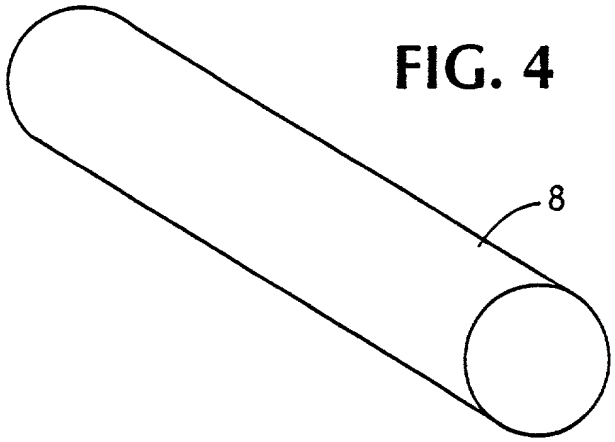

FIG. 5

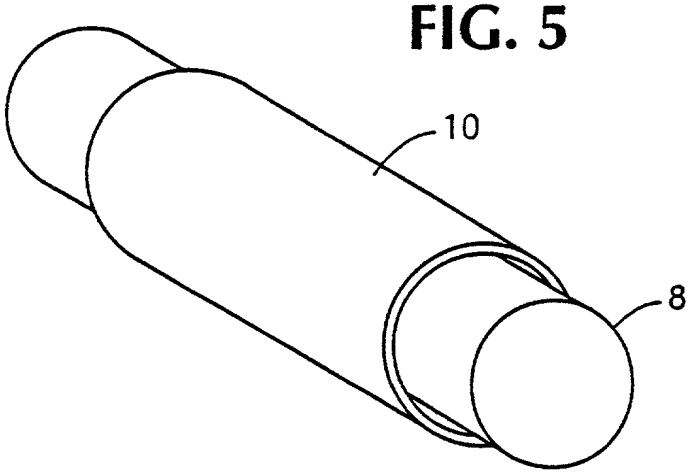

FIG. 6

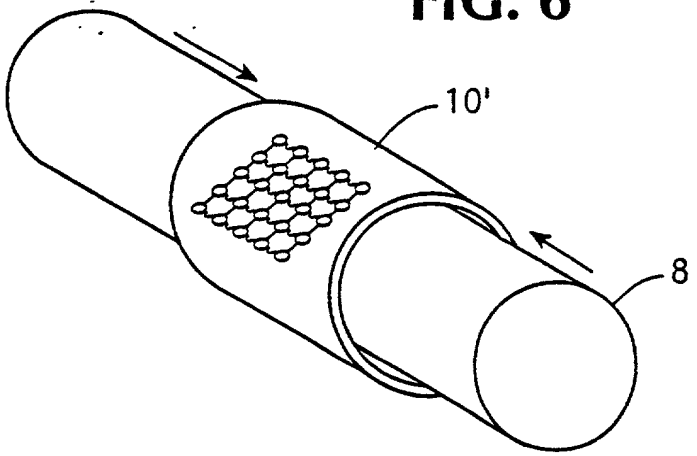

FIG. 7

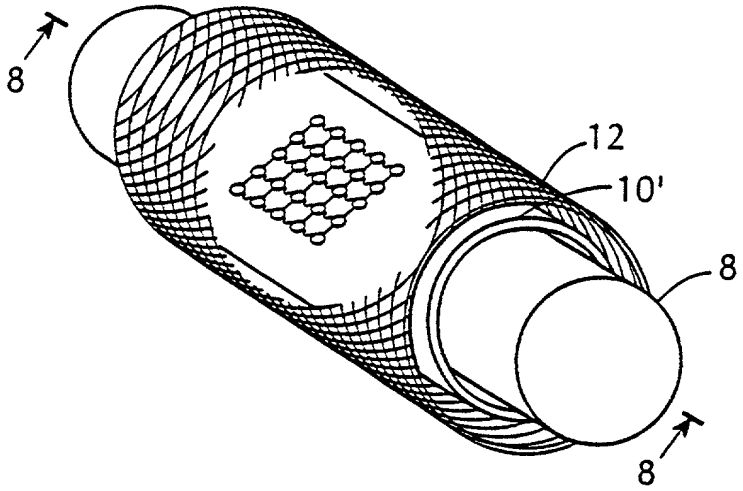

FIG. 8

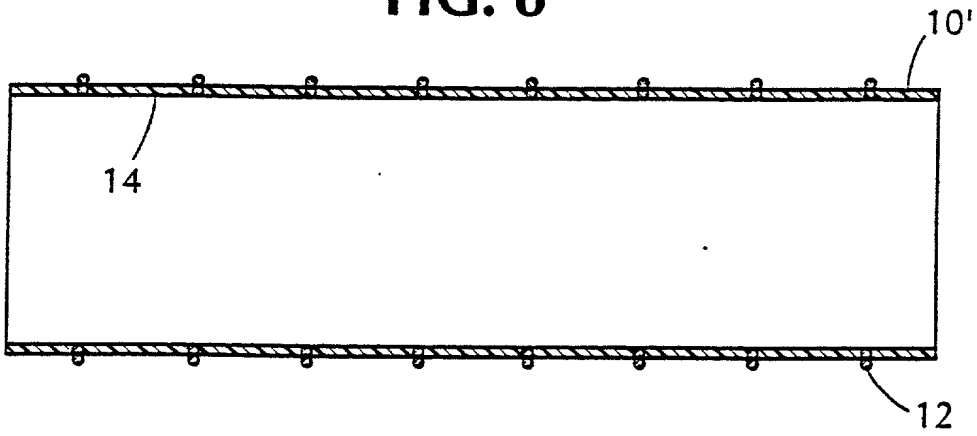

FIG. 9

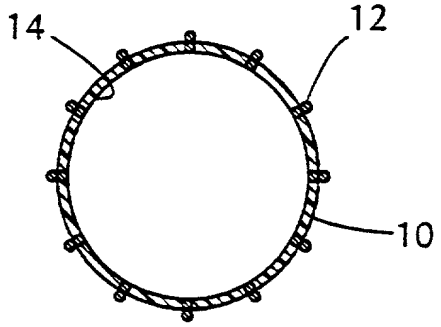

FIG. 10

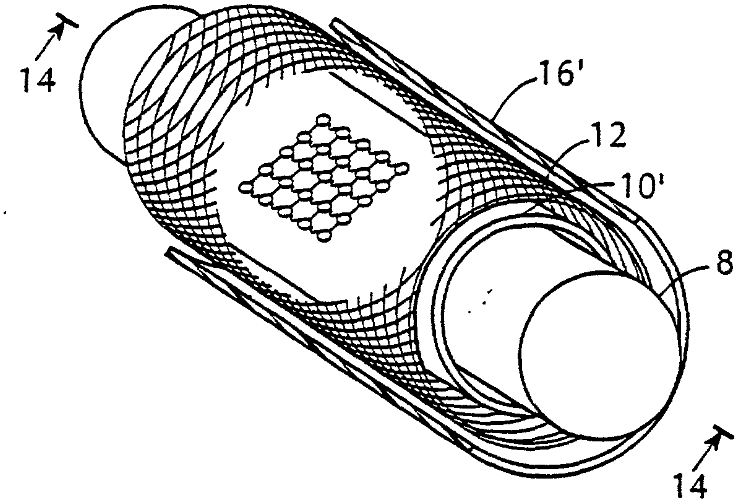

FIG. 11

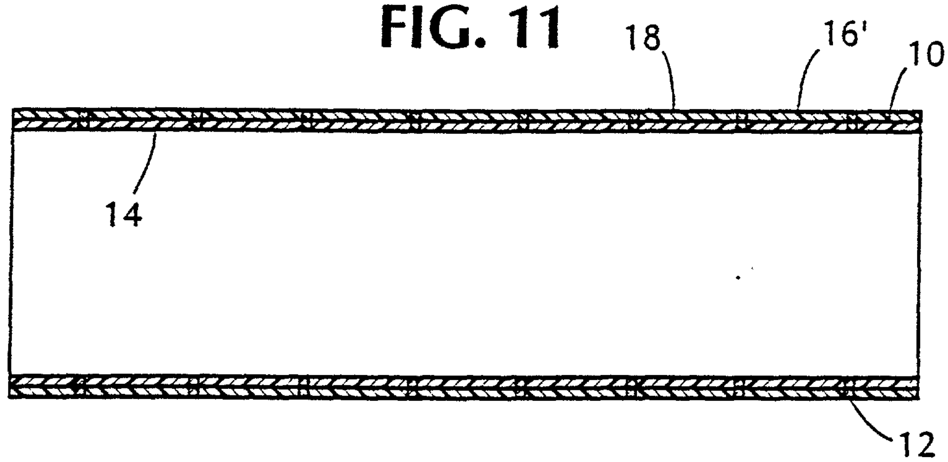

FIG. 12

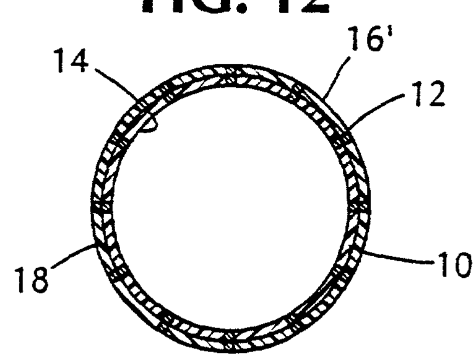

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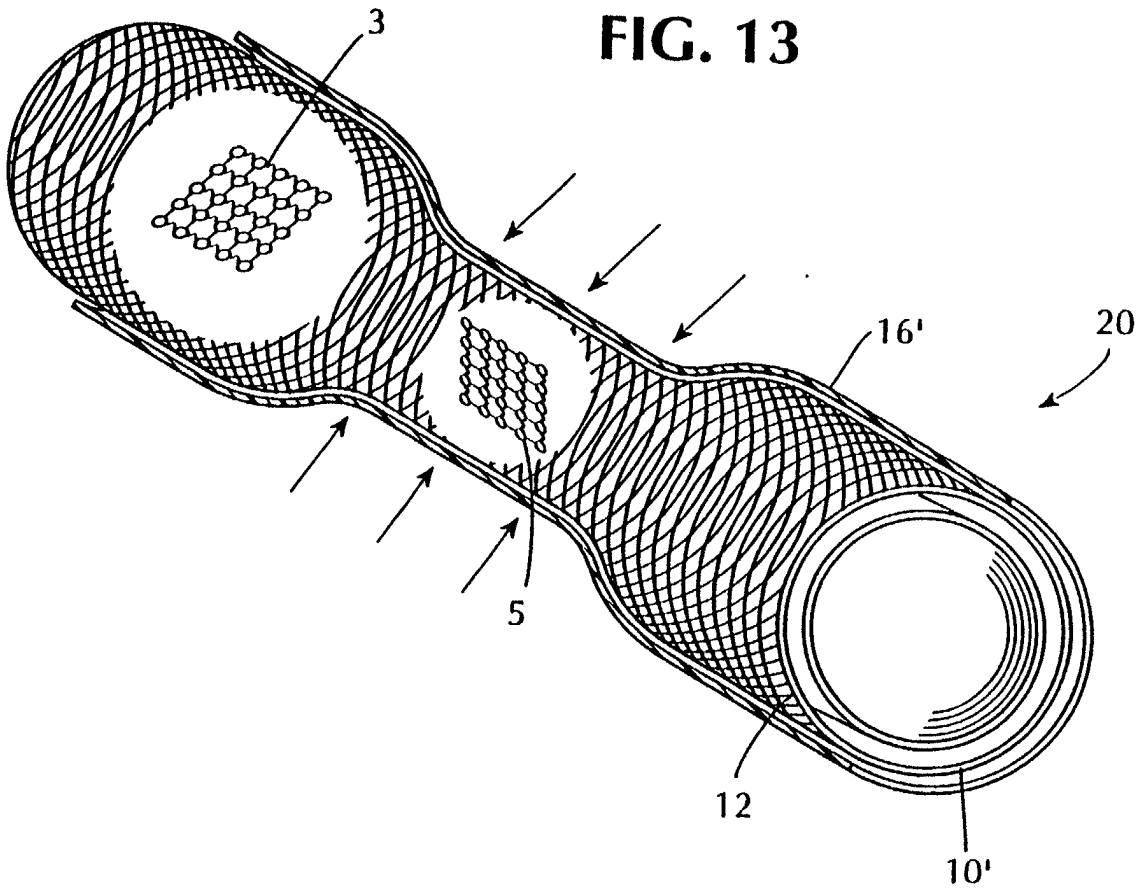
FIG. 13



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Express Mail No. EH808289055US

PC9221A
SOLE INVENTOR

DECLARATION AND POWER OF ATTORNEY

I, Paul J. Thompson, declare that I am a citizen of the United States of America and a resident of New Hope, Minnesota U.S.A.; that I verily believe I am the original, first, and sole inventor of the invention or discovery in

EXPANDABLE STENT-GRAFT COVERED WITH EXPANDED POLYTETRAFLUOROETHYLENE;

described and claimed in the attached United States patent application, that I do not know and do not believe that the same was ever known or used in the United States before my invention or discovery thereof, or patented or described in any printed publication in any country before my invention or discovery thereof, or more than one year prior to this application, or in public use or on sale in the United States more than one year prior to this application; that said invention or discovery has not been patented or made the subject of an inventor's certificate in any country foreign to the United States on an application filed by me or my legal representatives or assigns more than twelve months prior to this application; that I acknowledge that I have a duty to disclose information of which I am aware which is material to the examination of this application in accordance with Title 37, Code of Federal Regulations, Section 1.56(a); that I have reviewed and understand the contents of the specification, including the claims, as amended by any amendment(s) specifically referred to herein; and that no application for patent or inventor's certificate on said invention or discovery has been filed by me or my representatives or assigns in any country foreign to the United States, except as follows:

NONE

I further declare that all statements made herein of my own knowledge are true and that all statements made on information and belief are believed to be true; and further that these statements were made with the knowledge that willful false statements and the like so made are punishable by fine or imprisonment, or both, under Section 1001 of Title 18 of the United States Code and that such willful false statements may jeopardize the validity of the application or any patent issuing thereon;

And I hereby appoint PETER C. RICHARDSON, Reg. No. 27,526; ALLEN J. SPIEGEL, Reg. No. 25,749; AARON PASSMAN, Reg. No. 26,783; GEZINA HOLTRUST, Reg. No. 28,222; J. TREVOR LUMB, Reg. No. 28,567; LAWRENCE C. AKERS, Reg. No. 28,587; RAYMOND W. AUGUSTIN, Reg. No. 28,588; SEYMOUR G. BEKELNITZKY, Reg. No. 28,589; PAUL H. GINSBURG, Reg. No. 28,718; MARK DRYER, Reg. No. 28,775; ELIZABETH O. SLADE, Reg. No. 29,011; JOHN L. LAPIERRE, Reg. No. 29,185; JAMES T. JONES, Reg. No. 30,561; GREGG C. BENSON, Reg. No. 30,997; A. DEAN OLSON, Reg. No. 31,185; ROBERT F. SHEYKA, Reg. No. 31,304; HOWARD R. JAEGER, Reg. No. 31,376; GROVER F. FULLER, JR., Reg. No. 31,760; MERVIN E. BROKKE, Reg. No. 32,723; KAREN DEBENEDICTIS, Reg. No. 32,977; VALERIE M. FEDOWICH, Reg. No. 33,688; PHILIP C. STRASSBURGER, Reg. No. 34,258; BRYAN C. ZIELINSKI, Reg. No. 34,462; LORRAINE B. LING, Reg. No. 35,251; ROBERT T. RONAU, Reg. No. 36,257; GARTH BUTTERFIELD, Reg. No. 36,997; JOHN D. CONWAY, Reg. No. 39,150; B. TIMOTHY CREAGAN, Reg. No. 39,156; CARL J. GODDARD, Reg. No. 39,203 and ALAN L. KOLLER, Reg. No. 37,371; of Pfizer Inc., 235 East 42nd Street, New York, New York 10017-5755, my agents with full power of substitution, to prosecute this application and transact all business in the Patent and Trademark Office connected therewith.

And I hereby request that all correspondence in this application be directed to PETER C. RICHARDSON, Pfizer Inc., 235 East 42nd Street, New York, New York 10017-5755.

Wherefore I hereby subscribe my name to the foregoing specification and claims, declaration and power of attorney.

Signed the 15 day of November 1996

Inventor Paul J. Thompson

Paul J. Thompson

Post Office Address: 9125 40 and 1/2 Avenue North, New Hope, MN 55427

PATENT

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Applicant(s): Thompson, Paul J.

Examiner: Prebilic, P.

Serial No.: 08/988,725

Art Unit: 3738

Filed: December 11, 1997

Docket: 760-24 DIV

For: EXPANDED STENT-GRAFT COVERED WITH EXPANDED POLYTETRAFLUORO-ETHYLENE

I hereby certify this correspondence is being deposited with the United States Postal Service as first class mail, postpaid in an envelope, addressed to: Assistant Commissioner of Patents, Washington, D.C. 20231 on

Date: _____

Signature: _____

Assistant Commissioner for Patents
Washington, DC 20231

NEW POWER OF ATTORNEY BY ASSIGNEE (INCLUDING REVOCATION OF PRIOR POWERS OF ATTORNEY)

As assignee of record of the entire interest of the above-identified application, all powers of attorney previously given are hereby revoked. The following attorneys are hereby appointed to prosecute and transact all business in the U. S. Patent and Trademark Office in connection with this matter:

Charles R. Hoffmann, Reg. No. 24,102; Ronald J. Baron, Reg. No. 29,281; Gerald T. Bodner, Reg. No. 30,449; Alan M. Sack, Reg. No. 31,874; A. Thomas Kammer, Reg. No. 28,226; R. Glenn Schroeder, Reg. No. 34,720; Glenn T. Henneberger, Reg. No. 36,074; Irving N. Feit, Reg. No. 28,601; Anthony E. Bennett, Reg. No. 40,910; Gregory A. Bachmann, Reg. No. 41,593; Steven T. Zuschlag, Reg. No. 43,309, Susan A. Sipos, Reg. No. 43,128; Samir R. Patel, Reg. No. 44,998; James F. Harrington, Reg. No. 44,741 Kevin E. McDermott, Reg. No. 35,946; Roderick S.W. Turner, Reg. No. 38,639; Robert C. Morriss, Reg. No. 42,910; Richard LaCava, Reg. o. 41,135; Robert L. Bernstein, Reg. No. P-46,020; and Justin K. Holmes, Reg. No. 42,666, each of them of HOFFMANN & BARON, LLP, 6900 Jericho Turnpike, Syosset, New York 11791; and Daniel A. Scola, Jr., Reg. No. 29,855; Salvatore J. Abbruzzese, Reg. No 30,152; Kirk M. Miles, Reg. No. 37,891; Robert F. Chisholm, Reg. No. 39,939;

Kellyanne Merkel, Reg. No. 43,800; John S. Sopko, Reg. No. 41,321; Barry H. Jacobsen, Reg. No. 43,689; Mark E. Baron, Reg. No. P-46,150; and Keith R. Lange, Reg. No. 44,201, each of them of HOFFMANN & BARON, LLP, 1055 Parsippany Boulevard, Parsippany, New Jersey 07054.

Please address all future correspondence and telephone communications to:

Daniel A. Scola, Jr.
HOFFMANN & BARON, LLP
6900 Jericho Turnpike
Syosset, New York 11791
Tel: (973) 331-1700
Fax: (973) 331-1717

The assignee of the entire right, title and interest in this case is Schneider (USA) Inc., by virtue of assignment recorded in the U.S. Patent and Trademark Office on November 18, 1996 at Reel 8310, Frame 0415.

Attached to this power is a "Statement under 37 C.F.R. §3.73(b)".

Respectfully submitted,

Date: Feb 7, 00

Luke R. Dohmen

HOFFMANN & BARON, LLP
6900 Jericho Turnpike
Syosset, New York 11791
(973) 331-1700

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Dated: March 2, 2000

I hereby certify this correspondence is being deposited with the United States Postal Service as first class mail, postpaid in an envelope, addressed to Assistant Commissioner of Patents, Washington, D.C. 20231 on

Date March 2, 2000

Signature K.J. Goodhand / K. J. Goodhand

Assistant Commissioner for Patents
Washington, DC 20231

TRANSMITTAL OF NEW POWER OF ATTORNEY AND STATEMENT UNDER 37 C.F.R.§3.73(B)

Sir:

Please find enclosed a prepared Statement under 37 C.F.R.§3.73(b) establishing Schneider (USA) Inc. as the Assignee of the entire right, title and interest of the above-identified patent application, as well as the previously submitted Assignment documents. Please also find enclosed a new Power of Attorney executed by Assignee giving Power of Attorney to Hoffmann & Baron, LLP.

If you have any questions, please contact the undersigned at your convenience.

Respectfully submitted,

Mark E. Baron

Mark E. Baron
Registration No.: P-46,150
Attorney for Applicant(s)

HOFFMANN & BARON, LLP
6900 Jericho Turnpike
Syosset, New York 11791
(973) 331-1700

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Signature _____

Assistant Commissioner for Patents
Washington, DC 20231

STATEMENT UNDER 37 C.F.R. §3.73(b)

Schneider (USA) Inc., a Minnesota corporation, states that it is the assignee of the entire right, title, and interest in the above-identified patent application, by virtue of an assignment from the inventors of the application identified above. The assignment was recorded in the U.S. Patent and Trademark Office on November 18, 1996 at Reel 8310/Frame 0415.

The undersigned is empowered to sign this statement on behalf of the assignee.

Respectfully submitted,

Date: Feb 7, 00

Luke R. Dohmen

HOFFMANN & BARON, LLP
6900 Jericho Turnpike
Syosset, New York 11791
(973) 331-1700